K003951

MAR 2 1 2001

510(K) SUMMARY

1. SUBMITTER:

PectoFix, Inc.
2509 Park Avenue
South Plainfield, NJ 07080
Telephone: 800-776-1617

Contact: Eric Bannon, Regulatory
Date Prepared: December 12, 2000

2. DEVICE:

Classification Name: suture, nonabsorbable, steel, monofilament
Trade Name: PectoFix Sternal Repair Wire

3. PREDICATE DEVICE:

The predicate devices used to determine substantial equivalence for the PectoFix DSF System was the Ethicon USP #5 stainless steel suture, marketed by Ethicon, Inc., Somerville, NJ

4. DEVICE DESCRIPTION:

The PectoFix Sternal Repair Wire consists of USP stainless steel wire with and without needles. The product is offered in USP #6, 7 and 8 sizes meeting the corresponding USP requirements for stainless steel sutures. The product can be used independently for sternal repair or in conjunction with the sternal plates of the PectoFix Dynamic Sternal Fixation System.

Sutures are offered as sterile single use devices.

5. INTENDED USE:

The intended use of the PectoFix Sternal Repair Wire is for the repair of the sternum following median sternotomy.

6. COMPARISON OF CHARACTERISTICS:

The PectoFix Sternal Repair Wire is fabricated from stainless steel wire with and without needles. The Ethicon steel suture is fabricated from similar materials. Both products have needles attached through a swagging process and are offered for sale as sterile single use devices. The indications for use of the two devices are the same.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 21 2001

Mr. Eric Bannon
Regulatory
PectoFix, Inc.
2509 Park Avenue
South Plainfield, New Jersey 08840

Re: K003951
Trade Name: PectFix Sternal Repair Wire
Regulatory Class: II
Product Codes: JDQ
Dated: December 16, 2000
Received: December 21, 2000

Dear Mr. Bannon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

The intended use of the Dynamic Sternal Fixation System is for repair of the sternum following median sternotomy.

for Mark N Milkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003957